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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,600	05/16/2007	Alfred Niederberger	10139/08802	1693
30636	7590	03/02/2010	EXAMINER	
FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038				LAWSON, MATTHEW JAMES
ART UNIT		PAPER NUMBER		
3775				
		MAIL DATE		DELIVERY MODE
		03/02/2010		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/593,600	NIEDERBERGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MATTHEW LAWSON	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 11, 12, 14 and 16-30 is/are pending in the application.  
 4a) Of the above claim(s) 22-29 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 11-12, 14, 16-21, and 30 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/1/2010</u> .	6) <input type="checkbox"/> Other: _____. 

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 30 is rejected under 35 U.S.C. 102(e) as being anticipated by Landry et al. (US 2004/0143265).

Landry et al. disclose a bone screw comprising a head (118, figure 3), a cannulated shaft (figure 6) having a longitudinal axis (158, figures 11, 12a-12b), a proximal section (108, figures 2-3) adjoining the head wherein the proximal section is at least partially threaded (figures 2-3), and a distal section (112, figures 2-3) polyaxially associated with the proximal section (¶3, 152, figures 11, 12a-12b, and 13a).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12, 14, 16-19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mullane (US 6,050,997) in view of Landry et al. (US 2004/0143265).

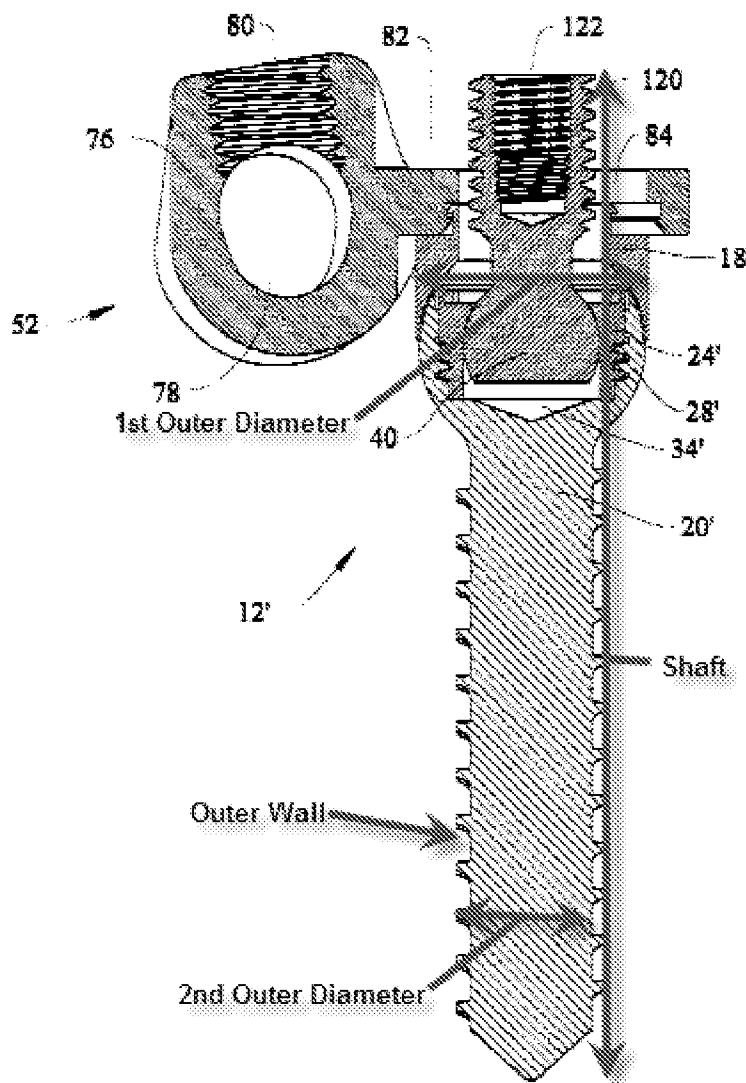
Mullane discloses a bone screw comprising a head 918, figure 14) having a first outer diameter (see figure below), and a shaft (see figure below) having a longitudinal axis, the cannulated shaft further comprising a proximal section (20', figure 14) adjoining the head and having a second outer diameter (see figure below) smaller than the first outer diameter, and outer wall (see figure below) of the proximal section being at least partially threaded (figure 14), and a distal section (120, figure 14) attached to the proximal section by way of a ball-and-socket joint (see abstract), wherein the distal section comprises the ball and the proximal section comprises the socket (figure 14), and the distal section is at least partially threaded (figure 14), and the length of the shaft is constant (figure 14) and the proximal section has a larger diameter than the distal section (figure 14), wherein the distal section is allowed to deflect no more than about 90 degrees relative to the longitudinal axis, preferably it is not allowed to deflect more than about 30 degrees relative to the longitudinal axis (figures 2-3, 14), wherein the distal section is rotatable relative to the proximal section about the longitudinal axis (column 7, lines 15-19).

Mullane fails to disclose the shaft being cannulated.

Landry et al. disclose a cannulated shaft (114, figure 6) to be used with a guide wire so that the shaft may be inserted into a vertebra at a desired location and in a desired angular orientation relative to the vertebra with limited or no visibility of the vertebrae (¶126). Accordingly it would have been obvious to one of ordinary skill in the

art at the time the invention was made to have constructed the screw of Mullane to be cannulated so that a guide wire could be used permitting for insertion and alignment with limited or no visibility of the surgical site as taught by Landry.

***FIG. 14***



Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mullane (US 6,050,997) in view of Landry et al. (US 2004/0143265) in further view of Purcell et al. (US 2004/0236330).

Mullane in view of Landry disclose the claimed invention except for the ball having an octagonal shape.

Purcell et al. disclose a bone screw comprising a head, a shaft having a longitudinal axis, a proximal section adjoining the head, and a distal section; wherein the distal section is attached to the proximal section by way of a ball-and-socket joint (abstract), wherein the ball has a substantially octagonal shape (figures 12-13, ¶39) to permit a variable angular relationship between the two portions (¶39). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the device of Mullane to have a ball with an octagonal shape as taught by Purcell et al. to permit a variable angle relationship between the two portions of the bone screw.

### ***Response to Arguments***

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW LAWSON whose telephone number is (571)270-7375. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MATTHEW LAWSON/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
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